Effect of a Tailored Physical Activity Intervention Delivered in General Practice Settings: Results of a Randomized Controlled Trial

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Objectives. We evaluated the effectiveness of a minimal intervention physical activity strategy (physician-based assessment and counseling for exercise [PACE]) applied in general practice settings in the Netherlands.

Methods. Randomization took place at the general practice level. Participants were patients aged 18–70 years of age who had been diagnosed with hypertension, hypercholesterolemia, or non–insulin-dependent diabetes and had not been regularly physically active in the past 6 months. Outcome measures were assessed at baseline and at 8-week, 6-month, and 1-year follow-ups.

Results. No significant intervention effect over time was observed on physical activity level or stage of change for regular physical activity, and an inverse intervention effect was observed for waist circumference. However, the study population as a whole exhibited a significant increase in physical activity and a borderline significant decrease in body weight at the 1-year follow-up.

Conclusions. Positive effects on physical activity level and body weight were observed, but the PACE intervention was not more effective than the standard physical activity advice. (*Am J Public Health.* 2005;95:1825–1831. doi:10.2105/AJPH.2004.044537)

Promotion of health-enhancing physical activity is considered one of the key components of public health. Numerous studies have shown that engaging in regular physical activity can prevent the onset of many chronic diseases, such as cardiovascular disease, non–insulin-dependent diabetes mellitus (NIDDM), coronary heart disease, and some forms of cancer.[1–4] Despite such evidence, more than half of the citizens of Western countries are insufficiently active, according to American College of Sports Medicine (ACSM) and Centers for Disease Control and Prevention (CDC) guidelines for regular physical activity (engaging in moderate-intensity physical activity for at least 30 minutes on 5, and preferably all, days of the week).[5,6]

Many interventions aimed at promoting physical activity have been developed and evaluated in the past few decades, and wide variations exist among these interventions. These interventions have been targeted toward different populations (e.g., children, elderly people, employees), have been implemented in different settings (e.g., hospitals, communities, schools), have involved different methods of delivery (e.g., face to face, mail, the Internet), and have been based on different theories (e.g., the transtheoretical model, the theory of planned behavior). In addition, levels of these interventions' success have varied,[7-10] and the search for effective interventions continues.

In the early 1990s, a promising physical activity intervention—physician-based assessment and counseling for exercise (PACE)[11]—was developed in the United States. PACE, based on the transtheoretical model of behavior change[12] and social–cognitive theory,[13] is a minimal intervention strategy aimed at promoting moderate-intensity physical activity with advice provided by primary care physicians. Because they see large numbers of patients on a regular basis and often have established long-lasting relationships with these individuals, primary care physicians (especially general practitioners) may be influential in changing patients' behaviors.[14]

However, primary care physicians note several important barriers to promotion of physical activity, including lack of time, lack of interest on the part of patients, lack of knowledge about physical activity, and lack of training in the area of behavioral counseling.[14–16] PACE aims to overcome these barriers through standard physician-delivered protocols that can be used in a short period of time. Futhermore, it provides physicians with training on physical activity promotion, and they are provided with a manual to assist them in offering advice to patients. The American version of PACE consists of a single visit to a primary care physician and a telephone "booster" call (in which encouragement is offered and problems or questions addressed) 2 weeks later. In a nonrandomized controlled trial, Calfas and colleagues[11] showed that PACE was effective in producing short-term increases in number of minutes walked among inactive individuals contemplating changes in their physical activity levels (the intervention group increased their physical activity by 37 minutes per week and the control group by 7 minutes). Furthermore, PACE has proven to be a feasible intervention in primary care settings in the United States.[15]

We conducted a randomized controlled trial designed to assess the effectiveness of a version of PACE implemented in Dutch general practice settings. Here we describe the extent to which the intervention affected participants' stage of change for regular physical activity (as described in the transtheoretical model),[12] level of physical activity, and body composition.

METHODS

Study Design and Population

The study was conducted in 29 volunteer general practices located throughout the

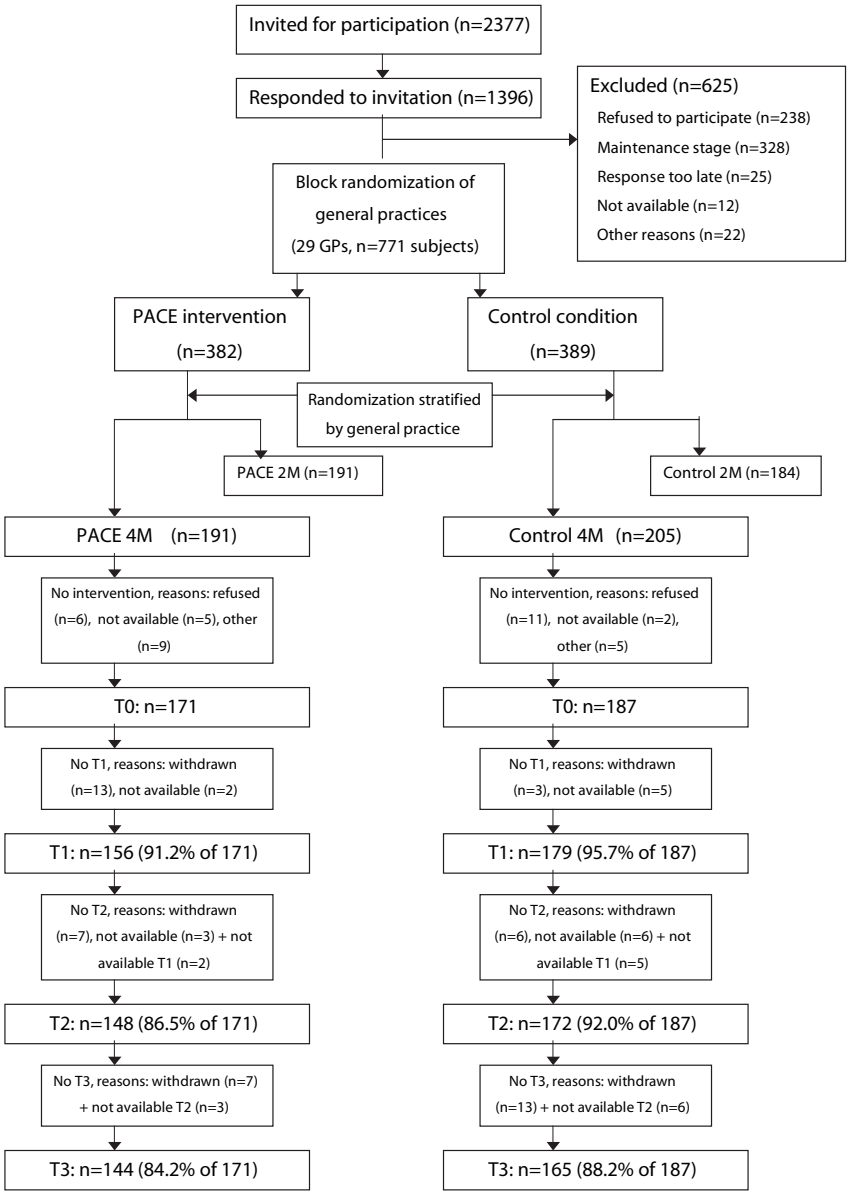
Netherlands. Both rural and city practices were included; no inclusion criteria were imposed on practices. Patients were eligible for the study if they (1) had been diagnosed with hypertension, hypercholesterolemia, or NIDDM (or any combination of these conditions); (2) were 18–70 years of age; (3) were able to participate in moderate-intensity physical activity; and (4) had not been physically active regularly in the past six months (i.e. not in the maintenance stage for regular physical activity).

Each general practitioner identified a target population on the basis of the inclusion criteria, and the research team randomly selected 90 patients per practice. The selected patients received a personal invitation letter from their general practitioner and an additional leaflet with more detailed information on the study. As a means of assessing willingness to participate and eligibility, patients were asked to return a stamped, addressed recruitment reply card on which they answered several questions, which were used to double-check the inclusion criteria. All patients were informed whether they would be included in the study. Approximately 25 patients per practice (range: 13–31) participated during the study inclusion period (October 2001–July 2002), with a 1-month inclusion period per practice.

Randomization

Randomization to the intervention and control conditions took place at the general practice level to prevent any influence of the intervention condition on the control patients. Practitioners were randomized in a block fashion (computer-generated blocks of 4 general practices per stratum) according to their own level of physical activity (i.e., whether they were at the level recommended by the ACSM/CDC physical activity guidelines). To rule out selection bias, we did not inform general practices of randomization outcomes until after the patient selection process.

Next, individual patients were randomized a second time to allow us to study the potential effect of the measurements conducted in the intervention evaluation. Half were randomized to a group participating in 4 measurements (baseline and follow-up measurements at 8 weeks, 6 months, and 1 year), and half were randomized to a group participating in only 2 measurements (6-month and 1-year follow-ups) (Figure 1). Patients were informed that randomization would take place, but they were not informed of the unit or outcome of randomizations. Only data from the patients randomized to the 4-measurement group were used in our analyses.



Note. PACE = physician-based assessment and counseling for exercise; PACE 4M = PACE intervention condition with measurements at baseline, 8 weeks, 6 months, and 1 year; PACE 2M = PACE intervention condition with measurement at 6 months and 1 year; control 4M = control condition with measurements at baseline, 8 weeks, 6 months, and 1 year; control 2M = control condition with measurement at 6 months and 1 year; not available = participant did not return questionnaire at follow-up measurement but was contacted for next measurements; GPs = general practitioners.

FIGURE 1—Flow of participants and distribution of nonresponders through the study.

Intervention

All patients were invited to visit their provider (general practitioner or nurse

practitioner) at baseline for a 10-minute consultation, irrespective of randomization status. In addition to discussing the patient's specific medical condition (hypertension, hypercholesterolemia, or NIDDM), the provider offered advice to the patient about becoming more physically active. In the intervention condition, the provider used the PACE physical activity program materials. (The PACE materials and the main intervention components have been described in detail elsewhere.[11,15,17])

In short, the Dutch version of PACE consisted of 2 visits with the provider and 2 booster telephone calls from a PACE physical activity counselor. At the first visit, patients filled out a stage assessment form (on which their PACE score was assessed on an 8-point scale) and 1 of 3 stage-specific counseling protocols (precontemplation, contemplation/preparation, or action/maintenance). Along with stage-specific information, each protocol contained questions that the patient was asked to answer before the provider visit. During the visit, the provider reviewed the protocol, counseled the patient (with an emphasis on stage-specific issues), and completed a registration form.

A PACE physical activity counselor telephoned the patient 2 weeks after the initial visit to provide encouragement and resolve possible problems or questions. A follow-up consultation with the provider was planned 4 weeks after the initial visit. During this consultation, the provider reviewed the registration form (and, in some cases, formulated a new counseling protocol) and discussed the patient's progression. A final booster telephone call, primarily aimed at relapse prevention, followed 8 weeks after this second visit.

Intervention providers completed a 1-hour individual training session. The main goals of this training were (1) to increase their knowledge of physical activity, health, and behavior change; (2) to introduce them to the PACE materials and allow them to practice using the materials; and (3) to provide answers to any questions they might have. Providers were contacted after their first PACE consultations to discuss problems or questions raised.

To standardize the usual care provided in the control condition, control providers were asked to briefly question patients about their current level of physical activity and, if appropriate, encourage them to become more physically active. Control providers were given a short standard example form on physical activity promotion to use in providing advice to their patients.

Measurements

Data on patients' levels of physical activity and changes in levels of physical activity were collected with questionnaires administered at baseline (before the first visit with the provider) and at the 8-week (T1), 6-month (T2), and 1-year (T3) follow-ups. Simple anthropometry measures (e.g., weight, waist circumference) were measured at baseline and at 2 follow-ups (T2 and T3). Practice assistants collected the questionnaires and performed anthropometry measurements at baseline; research assistants performed all follow-up measurements. Individuals who did not return questionnaires at a given follow-up visit but did not withdraw from the study were considered "not available" for that follow-up and were contacted for the next follow-up.

Outcome Measures

Stage of change. A questionnaire that included a 5-item scale was used to assess stage of change for regular moderate and vigorous physical activity. A total of 5 stages were distinguished in this questionnaire (precontemplation, contemplation, preparation, action, or maintenance) which has been proven to be both reliable and valid.[18] Change from baseline stage of change was dichotomized (progression vs stable/regression).

Physical activity level. The validated Short Questionnaire to Assess Health-enhancing physical activity (SQUASH) questionnaire was used to assess self-reported levels of physical activity[19]; participants were asked to recall an average week in the past month. Outcome values were number of minutes per week participants spent in physical activity of at least moderate intensity (4 or more metabolic equivalent [MET]), both overall and during leisure time (including commuting) and whether participants met the ACSM/CDC physical activity guidelines.

Body composition. Standard procedures were used to measure height, weight, and waist circumference. We calculated body mass index (BMI) by dividing weight in kilograms by height in meters squared.

Data Analysis

Intention-to-treat analyses were used to estimate the effects of the intervention. Longitudinal logistic regression analyses were used in examining dichotomous outcome measures, and longitudinal linear regression analyses were used in assessing all other outcome measures. The 3 follow-up measurements of the outcome measure concerned were defined as dependent variables. Because randomization took place at the level of general practices, multilevel analyses were used (the 3 analysis levels were the timing of follow-up measurement [2, 6, or 12 months], the individual, and the general practice).[20] This multilevel model allowed us to take into account the clustering of individuals within general practices and the clustering of the 3 follow-up measurements within individuals. In each case, baseline values of the dependent variables were included as covariates. Regression coefficients for group allocation variables (0=control, 1=intervention) reflected average differences in the outcome variables (adjusted for differences at baseline) over time. The Wald statistic was used in determining the statistical significance of intervention effects.

In a second analysis, the following baseline values were considered as possible confounders: gender, age, education level (defined as high, medium, or low), employment status (full time, part time, not employed), presence of children in household, smoking status (yes/no), and BMI (not included in analyses of body composition outcome measures). Baseline physical activity level (meeting or not meeting ACSM/CDC guidelines), smoking status, gender, age, and BMI were considered as possible effect modifiers. Effect modification was defined as a significant ($P<.10$) interaction between group allocation and the variable in question. Only significant effect modifiers are discussed in the Results. Multilevel modeling (2 levels: the individual and the general practice) was used to assess changes within the study population from baseline to the 1-year follow-up.

RESULTS

Study Population

Of 2377 invited patients, 1396 (59%) returned the recruitment reply card. Two hundred thirty-eight (17%) declined to participate, and 387 (28%) were excluded for various reasons (Figure 1). After group allocation at the general practice level and individual randomization of number of measurements, 191 participants were randomized to the intervention 4-measurement condition and 205 to the control 4-measurement condition. Of this group of 396 participants, 358 (90.4%) were available for the baseline measurement and were included in the study. At the 8-week follow-up (T1), 335 (93.6%) participants returned their questionnaires. Follow-up questionnaire return rates were 89.4% and 86.3% at 6 months (T2) and 1 year (T3), respectively.

The flow of participants through the study and the distribution of nonresponders are shown in Figure 1. At baseline, body composition data were collected from 344 participants (96.1%); collection rates at follow-up were 280 (81.4%) at T2 and 270 (78.5%) at T3. Thirty-three participants at T2 and 45 at T3 provided self-reported information on body composition. Independent-samples *t* tests did not show statistically significant differences between the values for the groups providing self-reported measurements and the groups measured by the research team (*P* values ranged from .110 to .859); thus, all participants were included in the analyses.

Table 1 presents the characteristics of the study population at baseline. No statistically significant differences between the 2 study groups were observed on the demographic variables assessed. Although between-group differences were not significant, control participants reported spending more minutes per week on physical activity at baseline. Also, a significantly higher percentage of participants in the control condition were classified as active by ACSM/CDC guidelines (*P*=.04).

TABLE 1—Baseline Characteristics and Stage of Change, Physical Activity Levels, and Body Composition: Control Group, PACE Intervention Group, and Overall Study Population

	Control Group (n = 187)	PACE Group (n = 171)	Total (n = 358)
Age, y, mean (SD)	55.3 (9.8)	55.7 (9.1)	55.5 (9.5)
Male, no. (%)	102 (54.5)	80 (46.8)	182 (50.8)
Employment status, no. (%)			
Employed full time	58 (32.2)	45 (26.9)	103 (29.7)
Employed part time	43 (23.9)	41 (24.6)	84 (24.2)
Unemployed	79 (43.9)	81 (48.5)	160 (46.1)
Education level, no. (%)			
Low	70 (38.0)	57 (34.8)	127 (36.5)
Medium	76 (41.3)	74 (45.1)	150 (43.1)
High	38 (20.7)	33 (20.1)	71 (20.4)
Stage of change, no. (%)			
Precontemplation	21 (11.2)	27 (15.8)	48 (13.4)
Contemplation/preparation	50 (26.7)	36 (21.0)	86 (24.0)
Action/maintenance	116 (62.0)	108 (63.2)	224 (62.6)
Physical activity			
Median minutes per week: total	330	240	300
Median minutes per week: leisure time	240	215	240
Meets ACSM/CDC guidelines,[a] no. (%)*	91 (49.2)	65 (38.2)	156 (43.9)
Body composition, mean (SD)			
Weight, kg	85.1 (15.2)	85.8 (17.9)	85.4 (16.5)
Body mass index, kg/m^2	28.6 (4.2)	29.3 (5.7)	28.9 (5.0)
Waist circumference, cm	98.3 (12.1)	97.9 (14.1)	98.1 (13.0)

Note. PACE = physician-based assessment and counseling for exercise; ACSM = American College of Sports Medicine; CDC = Centers for Disease Control and Prevention.
[a]Moderate physical activity for at least 30 minutes at least 5 days per week.
*P = .04 (difference between control and intervention groups).

Stage of Change

No statistically significant intervention effects over time were observed in progression from baseline stage of change (Table 2). The unadjusted data, however, showed that 35.3% of the participants had progressed at least 1 stage at T3 (control group: 34.5%; intervention group: 36.1%), and 79.9% were categorized in the action or maintenance stage at T3.

Physical Activity

No statistically significant intervention effects over time were observed in the physical activity outcome measures (adjusted differences from baseline in minutes per week spent in overall physical activity and in leisure time physical activity and percentage of participants who engaged in regular physical activity at a level consistent with the ACSM/CDC guidelines) (Table 2). However, both groups exhibited an overall increase in duration of physical activity from baseline through the 1-year follow-up (Figure 2). This increase was statistically significant for both total physical activity (mean increase: 61.6 minutes; 95% confidence interval [CI]=7.5, 115.6) and leisure time physical activity (mean increase: 61.8 minutes; 95% CI=24.5, 99.1).

Body Composition

No statistically significant intervention effects were observed for weight or BMI over the study period (Table 2). However, a statistically significant inverse intervention effect over time was observed for waist circumference; that is, waist circumference increased among intervention participants relative to control participants (adjusted change from baseline: 2.00; 95% CI=0.92, 3.07). A positive interaction was found with BMI at baseline (*P*=.09), indicating that the effect on waist circumference increased with increasing

TABLE 2—Results of Longitudinal Multilevel Analyses of the Effectiveness of the PACE (Physician-Based Assessment and Counseling for Exercise) Intervention Over 3 Follow-Ups

Outcome Measure	Crude Model[a] β or OR (95% CI)	*P*	Corrected Model[b] β or OR (95% CI)	*P*
Stage of change (progression of at least 1 stage)	1.48[c] (0.64, 3.44)	.36	1.50[c] (0.90, 2.50)	.12
Physical activity				
Minutes per week: total	−36.02[d] (−107.90, 35.87)	.33	−34.17[d] (−110.91, 42.56)	.38
Minutes per week: leisure	−33.56[d] (−88.07, 20.96)	.23	−36.46[d] (−93.47, 20.54)	.21
Meets ACSM/CDC guidelines	0.88[c] (0.56, 1.36)	.56	0.99[c] (0.62, 1.57)	.95
Body composition				
Weight, kg	0.19[d] (−0.52, 0.90)	.61	0.27[d] (−0.45, 1.00)	.46
Body mass index, kg/m^2	0.16[d] (−0.21, 0.53)	.40	0.21[d] (−0.14, 0.55)	.24
Waist circumference, cm	1.86[d] (0.81, 2.90)	<.001	2.00[d] (0.92, 3.07)	<.001

Note. OR = odds ratio; CI = confidence interval; ACSM = American College of Sports Medicine; CDC = Centers for Disease Control and Prevention. Values reflect average differences over time from baseline. Progression in stage of change and changes in the percentage of participants who met the ACSM/CDC physical activity guidelines were assessed via longitudinal logistic regression analyses; all other outcome measures were examined via longitudinal linear regression analyses. Odds ratios and 95% confidence intervals were calculated from estimates (and standard errors) of group allocation variables in the logistic regression model.

[a]Adjusted for group, time, and baseline value of outcome measure. Time was included in the model to account for the fact that outcome assessments were performed at irregularly spaced time points (i.e., 2, 6, and 12 months).

[b]Additionally adjusted for age, gender, employment, education, presence of children in household, and smoking status (physical activity outcome measures were also adjusted for body mass index at baseline).

[c]Odds ratio.

[d]β value.

BMI at baseline. An inverse interaction with time was also detected (*P*=.05), indicating that the inverse intervention effect weakened over time. The overall study population exhibited a nonsignificant decrease in weight over time (0.48 kg; 95% CI=−0.03, 1.00). No significant changes in BMI or waist circumference were observed among the participants overall.

DISCUSSION

The results of this study show that a version of the PACE intervention applied in general practices in the Netherlands was ineffective in producing positive intervention effects on level of regular physical activity, stage of change in activity, or body composition. On the contrary, an inverse effect over time was found for waist circumference. However, at 1 year, a statistically significant increase of 62 minutes per week spent in physical activity and a nonsignificant decrease in weight of 0.5 kg were observed in the study population.

The ineffectiveness of PACE in this study is consistent with the results of previous studies assessing the effectiveness of physical activity interventions in primary care settings,[7,10] but conflicts with the results of the first PACE study conducted in the United States.[11] In that study, intervention providers were selected as a consequence of their interest in physical activity promotion, only patients in the contemplation and preparation stages were included, the intervention was provided during a routine care visit, effectiveness was assessed only at a 6-week follow-up, and the investigation was designed as a nonrandomized controlled trial. Furthermore, by contrast with our study, the control providers in the American study did not offer physical activity advice but instead were trained in hepatitis B detection.[11]

Nevertheless, the results of the current study are consistent with a more recently conducted PACE study.[21] Although no intervention effects on physical activity outcome measures were observed in that study, increases in time spent in physical activity were observed in both the control and the intervention group. The authors attributed this result to seasonal influences and to contamination of the control providers, as they increased their physical activity counseling level during the study period instead of providing a usual care control condition in which this level remains stable.

We can only speculate about the reasons for the lack of an intervention effect in this study. The process evaluation revealed problems with the practical usage of the transtheoretical model.[17] Most intervention providers did not tailor their counseling to individual stages of change but instead discussed the same topics with all patients, which raises questions about the stage-based quality of the intervention. Also, staging relied on self-report, which involves the risk of misclassification.[22,23] An intervention based on an incorrect stage of change might not deliver the right message to the right person, and such occurrences may have affected our results.

Increases in physical activity levels among the control group have often been observed in randomized controlled trials promoting regular physical activity.[24–27] Several reasons have been proposed for this phenomenon, such as seasonal influences, the Hawthorne effect (i.e., behavior change as a result of study participation), regression to the mean, content of usual care, and possible effects of questionnaire and other measurement techniques. Some of these explanations can be ruled out with respect to the current study. Because both the intervention group and the control group were simultaneouly included between October 2001 and July 2002, seasonal influences would not have affected the results. Furthermore, although we found substantial differences in activity levels at baseline, we controlled regression to the mean by using baseline values of the outcome measures as covariates in all analyses.

Other explanations may be more plausible. First, as described in the Methods section, we assessed a mere measurement effect as part of the study. By comparing the 4-measurement group with the 2-measurement group at the 6-month follow-up, we were able to demonstrate a positive measurement effect on level of physical activity and awareness of meeting physical activity guidelines (E.M.F. van Sluijs, M.N.M. van Poppel, J.W.R. Twisk, and W. van Mechelen, unpublished data, 2005), which

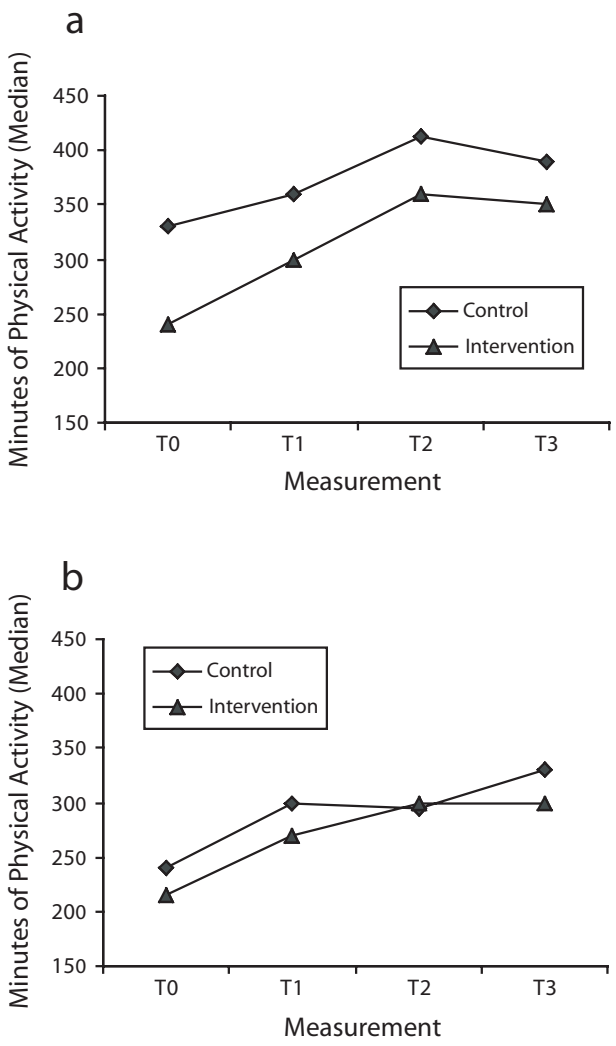


FIGURE 2—Median number of minutes spent per week in physical activity of at least moderate intensity: overall (a) and during leisure time (b) and in the PACE (physician-based assessment and counseling for exercise) intervention condition and the control condition at baseline (T0), 8 weeks (T1), 6 months (T2), and 1 year (T3).

may explain the observed increase in physical activity levels among the control participants. However, the measurement effect observed did not differ between the control and intervention groups, and thus it could not have had a major impact on the effect evaluation.

Second, the Hawthorne effect may have contributed to this increase as well; that is, participants could have changed their behaviors as a result of taking part in the study. Third, general practitioners in the control condition probably offered more physical activity advice to their patients than is usually the case. Other studies incorporating standardized physical activity advice in control conditions have also shown changes in levels of physical activity counseling.[20,23,25,26] It is unknown to what extent this difference in physicians' behavior might have affected the behavior of patients.

Whatever the reason, the finding that the study population as a whole exhibited significant increases in physical activity levels and clinically relevant decreases in body weight is both surprising and important from a public health point of view. Baseline levels of physical activity were high, considering the fact that we aimed to include a largely inactive population (i.e., individuals not in the maintenance stage of activity). Although one could argue that members of this self-selected population might have been highly motivated to change, it is surprising that this relatively active population showed an increase in physical activity level 1 year after baseline and that this increase resulted in a loss of body weight. Several influences may have contributed to this effect, and the PACE intervention was apparently not effective in producing additional effect.

On the basis of our results, we conclude that application of the PACE intervention in general practice settings is not effective in producing an additional effect on patients' levels of physical activity relative to standard advice provided by a physician. Nevertheless, from a public health point of view, it is very interesting to note that, against current physical activity and obesity trends,[5,28] the total study population became more physically active and lost weight. This finding suggests that increased attention on the part of providers to the topic of physical activity in Dutch general practice settings, possibly with added measurements of levels of physical activity and simple anthropometry, might already be having a positive influence on patients' physical activity levels. Because of the many benefits of a physically active lifestyle,[29] it may be worthwhile to encourage Dutch general practitioners to offer physical activity counseling and to provide them with training in doing so. ■

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Contributors

All of the authors contributed to the design and planning of the study. E.M.F. van Sluijs was responsible for data collection, analyzed the data, interpreted the findings, and drafted the article. M.N.M. van Poppel, M.J. Chin A Paw, and W. van Mechelen supervised the study, assisted with interpretation of the findings, and assisted in revisions of the article. J.W.R. Twisk advised on and assisted with the data analysis and interpretation of the findings and assisted with revisions of the article. K.J. Calfas assisted with interpretation of the findings and with revisions of the article.

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Human Participant Protection

The study protocol was approved by the Medical Ethical Committee of the VU University Medical Center, Amsterdam, the Netherlands. All participants provided written informed consent.

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